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April 18, 2000

FDA/Dockets Management Branch (HFA-305)
5630 Fishers Lane
Rm. 1061
Rockville, MD 20852

Subject: Comments on Docket No. 00N-0504, Egg Safety Action Plan

Dear Sir:

I have been involved with egg safety since the summer of 1996. My involvement includes helping with the development of the South Carolina Egg Quality Assurance Plan. I have taken and cultured environmental samples and egg samples. I participate in many of the national meetings on *Salmonella enteritidis* (SE).

I offer my comments on the proposed program.

1. Does the Egg Safety Action Plan comprehensively cover the problem of ES in eggs and measures for reducing this hazard?

No. The Action Plan is a rehash of the procedures that are already in place in most states. With the exception of the option offering a "lethal" step, the plan is passive and offers no change to the bacteria-carrier-vector-victim relationship. Under the currently approved system, after an outbreak of SE the farms supplying the eggs are tested for SE by drag swabbing the environment. If the environment is positive, eggs are diverted until 1000 eggs can be cultured and found to be negative for SE. Eggs can then be sold as shell eggs, however, three more tests must be done at two week intervals. In other words, we test until the tests are negative then we stop. This strategy implies that the eggs from a farm are a uniform lot. The fallacy is that the uniform lot for eggs is one egg. Using the accepted infection rate of 3 per 20000 eggs, finding infected eggs by culturing is both impractical and deceptive. The bottom line is that by testing eggs, we have changed nothing.

The accepted model for outbreaks of SE is that bacteria inside the egg contaminate food products. With the infection rate of 3 eggs in 20,000, it is difficult to balance the number of infected eggs with the number of outbreaks of SE. I believe that the model is valid, however, I believe that cross contamination, from bacteria outside the egg (the shell, the carton, the case) is equally important in this food borne zoonosis.

The Action Plan offers the option of a "lethal" step. In shell pasteurizers are being used to sterilize eggs. This process shows promise of being effective, however, it

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slows the processing of eggs and adds to the cost. It is too early to tell if the consumer will accept the end product.

What should be done to make the Plan more complete? I believe that environmental testing is essential to monitor any SE plan, however, I am opposed to any egg testing. I propose that any SE positive environmental sample results in diversion of eggs until an "intervention" has been done. An "intervention" is something that reduces the shedding of SE into eggs. One "intervention" would be to depopulate the flock and clean up the environment, however, the most promising step is vaccination. There are vaccines that have been shown to reduce the shedding of SE in the egg.

In the United Kingdom, SE has been a problem since the late 1980's. The first response by the Ministry of Agriculture, Food, and Fisheries was to do colocal swabs on all laying hens. If the swabs were positive for *Salmonella*, the hen was killed. This was an intervention, however, it did not work. In the late 1990's, the British egg industry adopted a plan similar to the proposed Action Plan and vaccinated the chickens. Through their efforts, SE has been sharply reduced in the United Kingdom.

In summary, I would like to remove egg testing from the Action Plan and add an "intervention" step.

2. What are the costs and benefits of implementing each risk reduction component of the Action Plan?

Most of the testing required by the Action Plan are already being paid for by the industry. Any additional testing adds costs.

The elimination of egg testing would eliminate a cost of \$2000 in testing charges per outbreak at our laboratory at current prices. The benefit would be the elimination of a false sense of security.

The costs of vaccination has been estimated to range from \$.02-.10 per bird. The benefit would be tremendous.

3. What training should be associated with respect to each component of the Action Plan?

I would emphasize that training is a necessary component.

4. Are the following appropriate and adequate components for a nationwide SE reduction program:

Bio-security	Yes
SE-negative feed	Yes
Chicks from SE-monitored breeders	No
Flock health monitoring program	Yes
Cleaning and disinfection of houses	Yes
Rodent/pest control	Yes
Monitored water supply	Yes

Chicks from SE-monitored breeders is another smoke screen. It is not adequate to have SE monitored chicks. Under the National Poultry Improvement Plan, breeders are monitored for SE. If there is an environmental positive for SE, sixty birds are killed and necropsy performed. Ten organs from each bird are cultured for SE. If that is negative, the process is complete (except for an increased testing schedule for several months), and it is business as usual.

I believe that any environmental positive sample should result in drug treatment of the breeders to eliminate SE, followed by competitive exclusion and vaccination. These eggs do not get into the human food chain, therefore, antibiotic treatment is warranted.

5. How effective do you think each component would be?

I believe that each component will be effective, but the problem will still persist without some type of intervention.

Which components do you think will provide the most risk reduction?

Rodent control is probably area that affords the greatest risk reduction. Rodent control affects lateral spread of the bacteria after it has been introduced into a house. I have a theory that the primary source of introduction of SE to a flock occurs prior to them entering the laying house.

6. Is environmental testing an appropriate verification step to ensure that the risk reduction plan is working? Yes

7. In the event that an environmental sample for SE is positive, what additional steps should a producer be required to take with the positive flock/house and with the next flock that will be placed in the house? I commented on this in #1 above. I believe that flocks coming into an environmentally positive house should be vaccinated, even though the house has been decontaminated.

8. Where vaccines have been used, is there a correlation between vaccine use and reduction of SE in eggs?

I believe that there would be a reduction, however, none of the flocks in South Carolina are vaccinated.

9., 10., 11., 12., 13., 14., 15., 16., 17. No Comment

18. Do the provisions in the 1999 Food Code which apply to shell eggs adequately protect at-risk consumers in retail establishments? I do not know what the provisions of the 1999 Food Code are, however, if they do not require that food handlers be periodically tested for *Salmonella*, *Listeria*, and *Escherichia coli* O157:H7, they are inadequate.

19. Rewashing of shell eggs is a wide-spread industry practice.

I take this to mean reworking eggs that have been sent to the retailer, but not sold. Under the South Carolina Egg Quality Assurance Plan (SCEQAP), this practice is not acceptable.

20. No Comment

21. All of the egg producers in South Carolina are under the South Carolina Egg Quality Assurance Plan and are doing all of these practices.

22. Testing for verification of the on farm plan.

a. To what extent are you currently testing?

The SCEQAP requires that houses be tested at least two weeks before depopulation.

b. What is the sampling plan for the tests you conduct?

Environmental samples consist of drag swabs of the manure. For high rise houses, swabs are taken of the tip of the cone. For belt manure systems, swabs are taken by running the manure belt for at least one complete cycle.

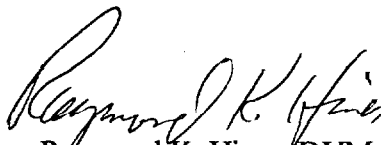
c. What test do you do?

Drag swabs are cultured using delayed enrichment. *Salmonella* positive samples are tested for the O type. Type D samples are sent to NVSL for speciation. Phage typing is sometimes done.

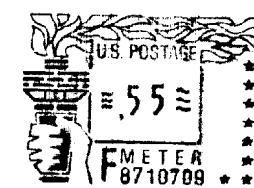
d. How much do these tests cost?

The lab charges \$5 per drag swab, however, actual costs are higher. Costs for on farm labor are not available.

23., 24., 25., 26., 27., 28., 29. No Comment


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